interest ''to a material degree.'' *44 Liquormart, Inc.* v. *Rhode Island,* 116 S. Ct. 1495, 1509 (1996) (plurality opinion of Justice Stevens) (citing *Edenfield* v. *Fane,* 507 U.S. 761, 771 (1993)). A commercial speech restriction that ''provides only ineffective or remote support for the government's purpose'' does not pass this test. *44 Liquormart,* 116 S. Ct. at 1509 (citing *Central Hudson,* 447 U.S. at 564).

The dubious efficacy of the proposed consumer education remedy makes it unlikely that it will directly advance the asserted governmental interest in preventing future deception by the respondent. In addition, I doubt that a credible argument can be made that the information that the order specifically requires be included in the brochure is no more extensive than necessary to prevent future violations by Schering. Certainly Schering has waived any First Amendment objections to this relief by entering into the consent agreement. Nonetheless, when a remedy implicates First Amendment rights, the Commission should be particularly reluctant to obtain through negotiations relief that it lacks at least a colorable chance to obtain in litigation.

In my view, it would be better to have no consumer information remedy in the consent order if the only alternative is an overbroad remedy of doubtful efficacy that raises First Amendment concerns.

[FR Doc. 97–5344 Filed 3–4–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Idaho National Engineering Laboratory Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Idaho National Engineering Laboratory Health Effects Subcommittee (INEL).

Times and Dates: 8:30 a.m.–5 p.m., March 20, 1997. 8:30 a.m.–5 p.m., March 21, 1997.

Place: Red Lion Inn-Riverside, 2900 Chinden Boulevard, Boise, Idaho 83714, telephone 208/343–1871, FAX 208/344–1079.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The Subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

Matters to be Discussed: Agenda items include presentations from the National Center for Environmental Health (NCEH) regarding current activities, the National Institute for Occupational Safety and Health, and ATSDR will provide updates on the progress of current studies, and working group discussions. Additional presentations will include prioritization and screening of chemicals for INEL dose reconstruction, discussions of screening methodology, and future dose reconstruction activities.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Arthur J. Robinson, Jr., or Nadine Dickerson, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–5400 Filed 3–4–97; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 95N–0329]

Preclearance of Promotional Labeling; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Biologics Evaluation and Research (CBER) is clarifying its policy regarding the preapproval of promotional labeling for biological products. In the November 1995 report issued by the President and Vice President, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' FDA made a commitment to harmonize immediately CBER's requirements for the preapproval of promotional labeling with those of the Center for Drug Evaluation and Research (CDER) under which a company may submit such information to the agency at the time the company disseminates it. This notice is issued to clarify that FDA has fulfilled the commitment to allow industry to submit promotional labeling to CBER at the time of initial dissemination. Sponsors need not wait for approval from CBER before using promotional labeling.

FOR FURTHER INFORMATION CONTACT: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028.

SUPPLEMENTARY INFORMATION: Under CBER's previous policy, as announced in the Federal Register of August 9, 1993 (58 FR 42340) and revised in the Federal Register of August 3, 1994 (59 FR 39570), preapproval by CBER was required for promotional labeling prior to introduction of a new biologic, for 120 days following approval of a new biologic, and for 120 days following approval of a new use for a currently licensed biologic. In the November 1995 report issued by the President and Vice President, ''Reinventing the Regulation of Drugs Made from Biotechnology,'' FDA made a commitment that, effective immediately, CBER would no longer require preapproval of promotional labeling. This approach, it was noted, is consistent with that of CDER. FDA has fulfilled its commitment.

In a proposed rule on changes to an approved application, published in the Federal Register of January 29, 1996 (61 FR 2739), FDA took a further step toward harmonizing the two Centers' promotional requirements. Among other things, the proposed rule would amend 21 CFR 601.12 to make CBER requirements for advertisements, as well as promotional labeling, consistent with those of CDER as set forth in 21 CFR 314.81(b)(3)(i).

The scope of this notice does not extend to promotional materials for products reviewed under the regulations for accelerated approval (21 CFR part 601, subpart E), which should be submitted to the agency for consideration as required in 21 CFR 601.45.

Dated: February 28, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–5311 Filed 3–4–97; 8:45 am]

BILLING CODE 4160–01–F